REMARKS

1. Status of the Claims

Claims 1-148 were filed in the present application. Claims 1-60 and 83-148 were canceled. Claims 149-164 are added by amendment herein. Applicants respectfully request that the Examiner enter new claims 149-164. Therefore, claims 61-82 and 149-164 are currently pending in the present application. Applicants respectfully request that the Examiner reconsider the presently pending claims in view of the amendments above and the remarks below.

2. All Prior Grounds of Rejection Have Been Withdrawn

Applicants note that all prior grounds of rejection have been withdrawn (see page 2, section 1 of the Office Action mailed December 04, 2003, hereinafter the "Action").

3. Claim Rejections under 35 U.S.C. § 112, First Paragraph

A. Enablement of claims 61-71, 73, 75, and 77-82.

Claims 61-71, 73, 75, and 77-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for accessory molecules selected from the costimulatory molecules B7.1 and B7.2, the adhesion molecules ICAM-1, ICAM-2, ICAM-3 and LFA-3 and the survival molecules Fas ligand and CD70, allegedly does not reasonably provide enablement of any and all types of accessory molecule. The present rejection is respectfully traversed.

The use of the term "any" in the context of "does not reasonably provide enablement for any and all types of accessory molecule" (emphasis added) is without merit and contradicts the Examiner's statement that the specification is enabling for certain accessory molecules. Thus, removing the term "any", the present rejection is based upon the assertion that the

specification allegedly does not provide enablement for "all types of accessory molecules". For example, the Examiner states on page 3 of the Action, "The specification does not teach molecules which participate in all aspects of antigen processing and presentation and therefore does not provide sufficient guidance to one of ordinary skill in the art to practice the claimed invention commensurate in scope with the recitation of 'accessory molecules'" (emphasis added).

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. There is no requirement in the test for enablement that all types of accessory molecules must be taught in the specification, only that one skilled in the art could make or use the invention without undue experimentation.

As admitted by the Examiner, the specification enables the use of at least eight different accessory molecules (see above). The specification further teaches generic accessory molecules for use in the present invention (see, e.g., page 21, line 4 through page 24, line 2). While not required for enablement, the specification does disclose working examples using a variety of accessory molecules (see e.g., page 83, line 10 through page 87, line 21). Also, the skill level of the ordinary artisan is exceptionally high with most practitioners having attained a doctoral level of expertise. Furthermore, the Examiner has failed to demonstrate that any experimentation is required to practice the claimed invention because the Examiner has failed to identify any accessory molecule known in the art at the time the application was filed which is not enabled by the discloses of the specification or by the knowledge available in the art. Therefore, the claimed invention is enabled in view of the high level of guidance provided in the specification including the enablement of at least eight different accessory molecules and

the provision of working examples, in view of the high level of skill of the artisan, and in view of the failure of the Examiner to demonstrate that experimentation is necessary to make and use the invention. Applicants respectfully request that the present rejection be withdrawn because a prima facie case of lack of enablement has not been demonstrated by the Examiner.

B. Possession of the Claimed Invention (61-67 and 70-82)

Claims 61-67 and 70-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. Applicants respectfully traverse the present rejection.

The Examiner asserts, "The written description in this case only sets forth insect cells that have been transformed to express MHC class II heterodimers and accessory molecules". Applicants respectfully traverse this rejection. The specification sets forth, for example, eukaryotic poikilothermic cells that have been transformed to express MHC class II heterodimers and accessory molecules (see, e.g., page 8, lines 4-31 of the specification). Thus, the inventors were in possession of the claimed invention because the use of eukaryotic poikilothermic cells is specifically disclosed in the specification, and the assertion that the use of eukaryotic poikilothermic cells is not disclosed is without merit.

The Examiner next asserts, "The instant specification does not describe other cell types, nor are vectors suitable for the transformation of non-insect cell types described". Again, the present assertion is without merit. The specification does describe "other" cell types, in particular, the claimed eukaryotic poikilothermic cells are described in the

specification (see above). A wide variety of vectors are also described in the specification (see, e.g., page 29,line 17 through page 40, line 13. Vectors described in the specification as useful for transformation of eukaryotic poikilothermic cells include, for example: eukaryotic cell expression vectors available from commercial sources (see, e.g., page 34, lines 22-23); pSV0, pKSV-10, pPVV-1/PML2d, and pTDT1 (see, e.g., page 34, lines 28-30); adenovirus expression vectors (see, e.g., page 37, lines 1-10); vaccinia virus vectors (see, e.g., page 37, lines 10-15); and bovine papilloma virus based vectors (see, e.g., page 37, lines 15-31). Thus, the specification does describe the claimed cells and vectors.

Applicants respectfully request that the present rejection be withdrawn because the specification demonstrates that the inventors were in possession of the claimed invention as discussed above.

C. Enablement of Poikilothermic Cells in claims 61-67 and 70-82.

Claims 61-67 and 70-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using synthetic MHC class II positive antigen presenting cells via transfection of insect cells, allegedly does not reasonably provide enablement for utilizing cells from other poikilothermic organisms. The present rejection is respectfully traversed.

The Examiner admits that, "The instant specification provides guidance by which the artisan can transfect insect cells with the MHC subunits and the accessory molecules and express said molecules on the surface of the insect cell".

The Examiner asserts, "However, the specification is not enabling for the transfection and use of other types of cells". The claims recite a method of producing an eukaryotic

poikilothermic synthetic antigen presenting cell; thus, there is no requirement that the specification enable "other types of cells", only eukaryotic poikilothermic cells. The specification specifically discloses the use of eukaryotic poikilothermic cells, for example, at page 8, lines 4-13.

The Examiner next asserts, "There is no disclosure of vectors which are suitable for transfection of other cell types, nor is there a disclosure of culture conditions, such as media supplements required, for the propagation and maintenance of non-insect poikilothermic cells. The present assertion is without merit. Vectors suitable for transfection of the claimed eukaryotic poikilothermic cells are disclosed in the specification (see the discussion above for specific references). Furthermore, the culture conditions for the propagation and maintenance of non-insect poikilothermic cells are well known in the art. There is no requirement that the specification disclose the media conditions for every type of the claimed cell when the skilled artisan is already in possession of such knowledge. Still further, if experimentation were required to determine the culture conditions for a particular desired eukaryotic poikilothermic cell type, such experimentation would not be undue because the art routinely participates in such experimentation.

The presently claimed invention is enabled in view of the lack of or limited amount of experimentation necessary to practice the invention, the provision of working examples (although not required), the high level of skill of the ordinary artisan, the relatively high degree of predictability in the art of gene transfection, and the high amount of guidance provided in the specification as detailed above. Applicants respectfully request that the present rejection be withdrawn because a prima facie case of lack of enablement has not been established by the Examiner.

CONCLUSION

The Applicant respectfully requests that the Examiner enter the present response herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

May 04, 2004
Date

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